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# Senate

The Senate met at 9:30 a.m., and was called to order by the President pro tempore [Mr. THURMOND].

## PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

Gracious Father, thank You for the stirrings in our minds and the longings in our hearts that are sure evidence that You are calling us into prayer. Long before we call, You answer by creating the desire to renew our relationship with You. You allow that feeling of emptiness in the pit of our being to alert us to our hunger for fellowship with You.

Our thirst for Your truth, our quest for Your solutions to our needs, and our yearning for Your answers to our problems are all assurances that before we articulated our prayers, You were preparing the answers. It is a magnificent, liberating thought that all through this day when we cry out for Your help, You have already been waiting for us to give up our persistent self-reliance and start drawing on the supernatural strength and superabundant wisdom You are so eager to give us.

Thank You for a day filled with serendipities of Your intervention. In the name of our Lord and Saviour. Amen.

## RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader is recognized.

## SCHEDULE

Mr. JEFFORDS. Mr. President, this morning the Senate is immediately resuming consideration of S. 830, the FDA reform legislation. In a moment we will begin two consecutive rollcall votes on or in relation to the pending amendments offered by Senator DURBIN. Following those votes, additional amendments are expected and therefore rollcall votes will occur throughout the day.

Under the consent agreement there are 5 hours remaining for debate prior to a vote on the pending substitute amendment. I hope that once the debate time has expired, the Senate will be able to proceed to a vote and then passage of this important legislation.

The majority leader has also stated that this week the Senate will consider the D.C. appropriations bill and any appropriations conference reports that become available.

I yield the floor.

## FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. HUTCHINSON). Under the previous order, the Senate will now resume consideration of S. 830, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to improve the regulation of foods, drugs, devices and biological products, and for other purposes.

The Senate resumed consideration of the bill.

Pending:

Jeffords amendment No. 1130, in the nature of a substitute.

Harkin amendment No. 1137 (to amendment No. 1130), authorizing funds for each of fiscal years 1998 through 2000 to establish within the National Institutes of Health an agency to be known as the National Center for Complementary and Alternative Medicine.

Durbin amendment No. 1140 (to amendment No. 1130), to require that entities and individuals accredited to conduct review of device notifications be subject to the conflict of interest standards that apply to employees of the Food and Drug Administration.

Durbin amendment No. 1139 (to amendment No. 1130), to eliminate provisions relating to the discretion of the Secretary of Health and Human Services to track devices or to conduct postmarket surveillance of devices.

### AMENDMENT NO. 1140

The PRESIDING OFFICER. The Senate will now resume consideration of the Durbin amendment No. 1140 with 2 minutes of debate prior to the vote.

The Senator from Illinois.

Mr. DURBIN. Mr. President, thank you for recognition this morning and the resumption of our consideration of this important bill.

Amendment No. 1140, which I have offered, is an amendment that I think is absolutely essential if this bill is to be airtight. We are giving to outside laboratories the authority to review and approve medical devices, medical devices which literally could mean life or death for millions of Americans.

When these approvals are given, these companies stand to make substantial profits because of FDA approval. The Durbin amendment corrects a serious error in this bill by making certain that there will be no conflict of interest by the third-party reviewers. We say in specific terms that those reviewing the medical devices cannot receive gifts from the company that is the owner of the medical device, they cannot receive or own stock of the company that they are reviewing, they cannot have been offered a job or solicited a job from the company that they are reviewing, and there must be a full financial disclosure.

If we are going to maintain the integrity of the process, protect American consumers, and avoid this sort of conflict of interest, I urge my colleagues to adopt the Durbin amendment.

Mr. JEFFORDS. Mr. President, the Senator's amendment at best duplicates the third-party conflict-of-interest protections in the bill and at worst unnecessarily constrains the agency. The ranking minority member, Senator KENNEDY, and the FDA join me in opposing this amendment.